General

Guideline Title

Diagnosis and management of asthma.

Bibliographic Source(s)

Sveum R, Bergstrom J, Brottman G, Hanson M, Heiman M, Johns K, Malkiewicz J, Manney S, Moyer L, Myers C, Myers N, Oâ€™Brien M, Rethwill M, Schaefer K, Uden D. Diagnosis and management of asthma. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2012 Jul. 86 p. [81 references]

Guideline Status

This is the current release of guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of asthma. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2010 Jun. 64 p.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- September 26, 2014 – Xolair (omalizumab) : A U.S. Food and Drug Administration (FDA) review of safety studies suggests a slightly increased risk of problems involving the heart and blood vessels supplying the brain among patients being treated with the asthma drug Xolair (omalizumab) than in those who were not treated with Xolair. As a result, FDA has added information about these potential risks to the drug label.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): For a description of what has changed since the previous version of this guidance, refer to Summary of Changes Report -- July 2012 . In addition, ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. This document

is in transition to the GRADE methodology. Transition steps incorporating GRADE methodology for this document include the following:

- Priority placed upon available systematic reviews in literature searches.
- All existing Class A (randomized controlled trials [RCTs]) studies have been considered as high quality evidence unless specified differently by a work group member.
- All existing Class B, C and D studies have been considered as low quality evidence unless specified differently by a work group member.
- All existing Class M and R studies are identified by study design versus assigning a quality of evidence. Refer to Crosswalk between ICSI Evidence Grading System and GRADE (see below in the "Definitions" section).
- All new literature considered by the work group for this revision has been assessed using GRADE methodology.

The recommendations for diagnosis and management of asthma are presented in the form of two algorithms with 32 components, accompanied by detailed annotations. Algorithms are provided in the original guideline document for Diagnosis and Management of Asthma (Main Algorithm) and Emergency Department or Inpatient Management. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Quality of evidence (Low Quality, Moderate Quality, High Quality, Meta-analysis, Systematic Review, Decision Analysis, Cost-Effectiveness Analysis, Guideline, and Reference) ratings are defined at the end of the "Major Recommendations" field.

Clinical Highlights

- Conduct interval evaluations of asthma including medical history and physical examination, assessment of asthma triggers and allergens, measurement of pulmonary function, and consideration of consultation and/or allergy testing. (*Annotation #11*)
- Assess control using objective measures and a validated asthma control tool. (*Annotation #12*)
- Match therapy with asthma control. (*Annotation #13*)
- Provide asthma education to patients and parents of pediatric patients. Education should include basic facts about asthma, how medications work, inhaler technique, a written action plan including home peak flow rate monitoring or a symptom diary, environmental control measures, and emphasis on the need for regular follow-up visits. (*Annotation #14*)

Diagnosis and Management of Asthma (Main Algorithm) Annotations

1. Patient Presents with Suggestive Symptoms of Asthma
   Refer to the original guideline document for definition of asthma.

   Symptoms

   - Wheezing
   - Breathlessness
   - Cough, productive or dry
   - Chest discomfort

   Pattern of Symptoms

   - Perennial/seasonal
   - Episodic/continual
   - Diurnal

   Severity of Symptom Classification

   - Number of symptom episodes per week
   - Number of nocturnal symptoms per month
   - Objective measures of lung function (forced expiratory volume in one second [FEV_1], peak expiratory flow rate [PEFR], PEF variability)

   Symptoms of Asthma

   Symptoms suggestive of asthma include episodic wheezing and cough with nocturnal, seasonal or exertional characteristics. Infants and children with frequent episodes of "bronchitis" are likely to have asthma. Atopic and positive family histories for asthma, particularly when associated with previously mentioned symptoms, should encourage one to consider a diagnosis of asthma.

   Eliciting symptoms should emphasize characterizing the current classification scheme that describes frequency per week, changes in physical activity, diurnal variation, and seasonal variation. It is important to recognize that patients with asthma are heterogeneous, falling into every age group, from infancy to older age, and presenting a spectrum of signs and symptoms that vary in degree and severity from patient to

patient as well as within an individual patient over time *[Guideline]*.

2. Previous Diagnosis of Asthma?
   At each evaluation, it is important to consider whether or not a previous diagnosis was correct.

   - History and physical consistent with diagnosis
   - Response to therapy consistent with symptoms

3. Establish Diagnosis of Asthma and Determine Level of Severity
   Recommendations:

   - The diagnosis of asthma is based on the patient's medical history, physical examination, pulmonary function tests, and laboratory test results.
   - Spirometry is recommended for the diagnosis of asthma.
   - The level of asthma severity is determined by both impairment and risk.

   Asthma Triggers

   - Viral respiratory infections
   - Environmental allergens
   - Exercise, temperature, humidity
   - Occupational and recreational allergens or irritants
   - Environmental irritants (perfume, tobacco smoke, wood burning stoves)
   - Drugs (aspirin, nonsteroidal anti-inflammatory drugs [NSAIDs], beta-blocker) and food (sulfites)

   Other Historical Components

   - Emergency room visits and hospitalization
   - Medication use (especially oral steroids)
   - Lung function, PEFR variability
   - Associated comorbidities (e.g., rhinitis, sinusitis, gastroesophageal reflux disease [GERD])

   Clinical Testing

   - Accurate spirometry is recommended in every patient 5 years of age or older at the time of diagnosis.
   - Additional studies done, tailored to the specific patient.
     - Allergy testing (skin testing, blood testing, in vitro specific immunoglobulin E [IgE] antibody testing)
     - Chest radiography, to exclude alternative diagnosis
     - Bronchial provocation testing if spirometry is normal or near normal
     - Sinus x-rays or computed tomography (CT) scan
     - GERD evaluation
     - Complete blood count (CBC) with eosinophils, total IgE, sputum exam
     - Exhaled nitric oxide

   Spirometry is the cornerstone of the laboratory evaluation that enables the clinician to demonstrate airflow obstruction and establish a diagnosis of asthma with certainty. Spirometry is essential for assessing the severity of asthma in order to make appropriate therapeutic recommendations. The use of objective measures of lung function is recommended because patient-reported symptoms often do not correlate with the variability and severity of airflow obstruction. Testing should be performed in compliance with the American Thoracic Society standards. Obstructive and restrictive ventilatory defects can generally be determined using FEV_1/forced vital capacity (FVC) ratio *[Low Quality Evidence]*.

   Spirometry is generally valuable in children 5 years of age or older; however, some children cannot conduct the maneuver, depending on developmental ability. Spirometry measurements (FEV_1, FVC, and FEV_1/FVC) before or after the patient inhales a short-acting bronchodilator should be undertaken for patients in whom the diagnosis of asthma is being considered. Airflow obstruction is indicated by reduced FEV_1 and FEV_1/FVC values relative to reference or predicted values. Significant reversibility is indicated by an increase of 12 percent or greater and 200 mL in FEV_1 after inhaling a short-acting bronchodilator.

   Diagnostic spirometry and a methacholine challenge test, if necessary, are important to clinching the diagnosis. The patient's history and response to therapy should guide other diagnostic tests when considering alternative diagnoses. Follow-up spirometry every one to two years in mild asthmatics will reconfirm the diagnosis and objectify serial change and level of control. More frequent monitoring should be considered for the moderate and severe persistent categories.

Investigation into the role of allergy, at least with a complete history, should be done in every patient, given high prevalence of positive skin tests among individuals with asthma and the benefits of limiting exposure to known allergens. History may help to distinguish seasonal allergies but may be inadequate for perennial allergies. Eosinophil count and IgE may be elevated in asthma; however, neither test has sufficient specificity or sensitivity to be used alone in a diagnosis. The chest x-ray and electrocardiogram are usually normal in asthma but may be useful to exclude other pulmonary or cardiac conditions. Sputum examination may be helpful if sputum eosinophilia or infection are suspected.

Exhaled nitric oxide is a newly available quantitative, non-invasive measure of airway inflammation that is another tool to assess airway disease. The early use will be by asthma specialists rather than primary care. It can be useful in the diagnosis of eosinophilic airway inflammation as well as determining the likelihood of response to corticosteroid treatment, monitoring the airway to determine if additional anti-inflammatory is needed, and assisting in evaluating adherence to anti-inflammatory medication. The American Thoracic Society has published a clinical practice guideline: "Interpretation of Exhaled Nitric Oxide Levels for Clinical Application" *[Guideline]*.

There are several clinical scenarios in children that have a frequent association with asthma and should strongly suggest asthma as a possible diagnosis. These include recurrent pulmonary infiltrates (especially right middle lobe infiltrates) with volume loss that clear radiologically within two to three days, and the diagnosis of pneumonia without fever. Asthma may cause radiologic uncertainty since mucus plugging and atelectasis may be interpreted as infiltrates.

See Table 1, "Classifying Asthma Severity in Children 5-11 Years," and Table 2, "Classifying Asthma Severity in Youths and Adults," in the original guideline document.

(See the original guideline document for additional information concerning differential diagnostic possibilities for asthma.)

4. Acute Asthma Exacerbation?
   Symptoms of an acute asthma episode include progressive breathlessness, cough, wheezing, or chest tightness. An acute asthma episode is characterized by a decrease in expiratory airflow that can be documented and quantified by measurement of lung function (spirometry or PEFR). Indications for emergency care include:

   - Peak flow less than 40% predicted normal
   - Failure to respond to a $beta_2$-agonist
   - Severe wheezing or coughing
   - Extreme anxiety due to breathlessness
   - Gasping for air, sweaty, or cyanotic
   - Rapid deterioration over a few hours
   - Severe retractions and nasal flaring
   - Hunched forward

5. Assess Severity of Asthma Exacerbation
   Recommendations

   - Asthma severity must be promptly assessed using history, physical examination and objective measures of lung function during an exacerbation.
   - Assess patient severity for risk of death from current exacerbation based on history, pulse oximetry, signs of respiratory distress, and spirometry.
   - Assess patient for severity based on impairment using age-appropriate measures.
   - Assess patient for severity of asthma based on future risk of exacerbation using age-appropriate measures.
   - Spirometry is the preferred method for objective measurement of severity in acute exacerbation. $FEV_{1/}FVC$ ratio is the preferred method for objective measurement of lung function, especially in children.
   - Peak flow has not been found to be a reliable measure of severity in acute exacerbation *[Low Quality Evidence]*, *[High Quality Evidence]*.

   History

   - Symptoms consistent with asthma
   - Severity of symptoms, limitations, and sleep disturbance
   - Duration of symptoms
   - Current medical treatment plan

- Adherence to medical treatment plan
- Rescue medication use
  - Recent use of short acting $beta_2$-agonists
  - Number of bursts of oral steroids in past year
- Review Asthma Action Plan and daily charting of peak flows
  - A difference of up to 35% was found to separate FEV_1 and peak flow percent predicted in acute exacerbation *[Low Quality Evidence]*.
  - Peak flow rate has been shown unreliable for the classification of asthma severity *[High Quality Evidence]*.
- Previous emergency department (ED) visits or hospitalization
- Record triggers:
  - Upper respiratory infection (URI)
  - Bronchitis, pneumonia, sinusitis
  - Exposure to allergens or irritants
  - Assessment of tobacco use and/or second-hand exposure
  - Exercise
  - GERD

Clinicians treating asthma exacerbations should be familiar with the characteristics of patients at risk for life-threatening deterioration. See Table 3, "Risk Factors for Death from Asthma," in the original guideline document.

Lung Function

- Spirometry (FEV_1) – preferred, FEV_1/FVC preferred in children
- Pulse oximetry

Physical Exam

- Vital signs: temperature, blood pressure, pulse rate, respiratory rate, pulsus paradoxus
- Alertness
- Ability to talk
- Use of accessory muscles
- Auscultation of chest
- Color

Laboratory Studies

Treatment with bronchodilators should not be delayed for laboratory studies. Tests which may be useful include:

- Arterial blood gases (ABGs)
- Chest x-ray (CXR)
- CBC
- Electrocardiogram (EKG)
- Electrolytes
- Theophylline level (if appropriate)

See Table 4, "Assessment of Severity," in the original guideline document.

8. Management of Asthma Exacerbation

Recommendations

- Treatment is begun with inhaled short-acting $beta_2$-agonists administered by metered dose inhaler (MDI)/spacer or nebulizer.
- Further intensification of therapy is based on severity, response and prior history, but typically includes a short course of oral corticosteroids

[Low Quality Evidence]

Treatment

Usual initial treatment is with short-acting $beta_2$-agonist (albuterol) administered by nebulizer or MDI/spacer.

- Nebulized albuterol (2.5 mg/3 mL); depending on response to therapy, this dose may be repeated at 20-minute intervals for up to three times.

- Albuterol MDI/spacer 2 to 6 puffs; depending on response to therapy, this dose may be repeated at 20-minute intervals for up to three times.

[Guideline], *[Meta-analysis]*

Alternatives

Levalbuterol

- Nebulized levalbuterol (1.25 mg/3 mL); depending on response to therapy, this dose may be repeated three times at 20 minute intervals.
- Levalbuterol MDI/spacer 2 to 6 puffs; depending on response to therapy, this dose may be repeated three times at 20 minute intervals.
  - Dose for those over 12 years of age is 0.63 mg (via nebulizer) three times daily (every 6 to 8 hours). If patient does not exhibit adequate response, may increase dose to 1.25 mg via nebulizer three times daily (every 6 to 8 hours).
  - Dose for children 6 to 11 years of age is 0.31 mg (via nebulizer) three times daily. Routine dosing should not exceed 0.63 mg three times daily.

Ipratropium added to nebulized $beta_2$-agonist (albuterol)

- Nebulized dose for adults and those over 12 years of age is 0.5 mg every 4 hours. Not U.S. Food and Drug Administration (FDA)-approved for any indication in those under 12 years of age.
- Ipratropium is not currently FDA-approved for use in asthma.

Epinephrine (1:1000)

- Adults: 0.3 to 0.5 mg subcutaneous or intramuscular (IM) injections every 20 minutes up to three doses.
- Pediatrics: 0.01 mg/kg up to 0.3 to 0.5 mg subcutaneously or IM every 20 minutes up to three doses.

Corticosteroids (see Appendix A, "Dosages of Drugs for Asthma Exacerbations in Emergency Medical Care or Hospital," in the original guideline document for dosage recommendations)

- Strongly consider systemic corticosteroids in patients with acute asthma exacerbation. Corticosteroids aid symptom resolution and prevent asthma relapse *[High Quality Evidence]*.

Note: Do not use long-acting beta agonist (LABA) monotherapy in acute asthma exacerbations. See http://www.fda.gov/Drugs/DrugSafety/SafeUseInitiative/default.htm (Accessed April 24, 2012).

- Initiate inhaled corticosteroids to prevent future exacerbations.

Antibiotics are not recommended for the treatment of acute asthma except for those patients with signs of acute bacterial infection, fever and purulent sputum.

9. Assess Response to Treatment
   Good Response
   - PEFR or FEV_1 greater than or equal to 70% predicted normal
   - No wheezing on auscultation

   Incomplete Response
   - PEFR or FEV_1 40% to 69% predicted
   - Mild wheezing
   - Consider hospitalization, particularly for high-risk patients

   Poor Response
   - PEFR or FEV_1 less than 40% predicted normal
   - No improvement in respiratory distress
   - Strongly consider hospitalization

10. Does Patient Need ED or Inpatient Asthma Management?
    Studies suggest that most children who require hospitalization can be identified by a repeat assessment one hour after initial treatment *[Low Quality Evidence]*. After one hour, those children who continue to meet the criteria for a severe exacerbation have a greater than 86% chance of requiring hospitalization; those who meet the criteria for moderate exacerbation at one hour have an 84% chance of requiring hospitalization; and those whose assessment has remained the same or dropped to the mild level have only an 18% chance of requiring

hospitalization. These severity assessment studies highlight the importance of regular, multifaceted assessments and close observation of children and adolescents who present to the office or ED with acute asthma exacerbations *[Guideline]*.

11. Evaluation

Recommendations

Evaluation of asthma should include the following:

- Medical history
- Use of a validated asthma questionnaire. Three validated tools are Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ) and Asthma Therapy Assessment Questionnaire (ATAQ).
- Assess indoor and outdoor asthma triggers/allergens
- Physical examination
- Measure lung function
- Consider specialty consultation

Medical History

- Disruption of usual activities (work, school, home)
- Sleep disturbance
- Level of usage of short-acting beta$_2$-agonist
- Adherence to medical treatment plan
- Interval exacerbation of symptoms (either treated by self or a health care provider)
- Symptoms suggesting comorbid conditions or alternative diagnosis
- Side effects of medications

Reassessment of medical history can elicit factors that affect overall asthma control and sense of well-being *[Low Quality Evidence]*. The key symptoms that should alert the clinician include disruptive daytime symptoms and disturbances of sleep, and symptoms early in the morning that do not improve 15 minutes after using short-acting beta$_2$-agonist. The quantity of short-acting beta$_2$-agonist that is being used should be discussed since overuse can be a marker of the potentially fatality-prone asthmatic *[Low Quality Evidence]*. The use of a quality of life tool or questionnaire can assist to elicit history *[Low Quality Evidence]*.

Use of a Validated Asthma Questionnaire

The self-assessment questionnaires that can be completed at office visits are intended to capture the patient's and family's impression of asthma control, self-management skills, and overall satisfaction with care. Three multidimensional instruments have been developed and validated for assessment and monitoring of asthma. They are the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ) and Asthma Therapy Assessment Questionnaire (ATAQ). Only the ACT has been validated for use with children ages 4 to 11. See http://www.nhlbi.nih.gov/guidelines/asthma/index.htm (Accessed April 24, 2012) *[Low Quality Evidence]*.

Assess Asthma Triggers/Allergens

- Inquire about exposure to triggers and allergens (e.g., occupational, pets, smoke).
- Allergy testing is recommended for patients with persistent asthma who are exposed to perennial indoor allergens.

Studies of emergency department visits and near death show allergens as a factor in asthma exacerbation. Asthma triggers in the workplace also need to be considered. About 15% of asthma in adults is work related *[Low Quality Evidence]*.

Physical Examination

- Assess signs associated with asthma, concurrent illness, or medication side effects
- Height in children
- Head, eyes, ears, nose, throat, lungs, heart, skin

It is important to discuss any potential medication side effects as this often has a direct relationship to compliance. See Annotation #14, "Asthma Education," for more guidance on side effects.

The remainder of the physical exam either supports or refutes conditions and comorbidities discussed above (see history).

Measure Lung Function

It is important to measure lung function at each asthma-related visit. The two main methods are spirometry and PEFR. Spirometry is more

precise and yields more information than PEFR. It is helpful to verify the accuracy of the peak flow meter. It is useful when certain physical limitations affect accuracy of PEFR (example: very young or elderly, neuromuscular or orthopedic problems) *[Low Quality Evidence]*.

Spirometry is recommended:

- For initial diagnosis or to reassess or confirm diagnosis
- After treatment is initiated or changed, and once symptoms and PEFR have stabilized to document attainment of "near normal pulmonary function"
- At least every 1 to 2 years to assess maintenance of airway function; more often as severity indicates.

Regular monitoring of pulmonary function is particularly important for asthma patients who do not perceive their symptoms until obstruction is severe *[Low Quality Evidence]*.

PEFR:

- Used for follow-up, not for diagnosis

PEFR provides a simple, quantitative, and reproductive measure of severity of airflow obstruction. The results are more reliable if the same type of meter, and preferably the patient's own, is used.

During interval assessment, the clinician should question the patient and review records to evaluate the frequency, severity, and causes of exacerbation. Triggers that may contribute should be reviewed. All patients on chronic maintenance medication should be questioned about exposure to inhalant allergens.

Consider Specialty Consultation

Referral is recommended for consultation or care to a specialist in asthma care (allergist or pulmonologist, or other physicians who have expertise in asthma management, developed through additional training and experience) *[Low Quality Evidence]* when:

- Patient has had a life-threatening asthma exacerbation.
- Patient is not meeting the goals of asthma therapy after 3 to 6 months of treatment. An earlier referral or consultation is appropriate if the physician concludes that the patient is unresponsive to therapy.
- Signs and symptoms are atypical, or there are problems in differential diagnosis.
- Other conditions complicate asthma or its diagnosis (e.g., sinusitis, nasal polyps, aspergillosis, severe rhinitis, vocal cord dysfunction [VCD], GERD, chronic obstructive pulmonary disease [COPD]).
- Additional diagnostic testing is indicated (e.g., allergy skin testing, rhinoscopy, complete pulmonary function studies, provocative challenge, bronchoscopy).
- Patient requires additional education and guidance on complications of therapy, problems with adherence, or allergen avoidance.
- Patient is being considered for immunotherapy.
- Patient requires step 4 care or higher. Consider referral if patient requires step 3 care.
- Patient has required more than two bursts of oral corticosteroids in one year or has an exacerbation requiring hospitalization.
- Patient requires confirmation of a history that suggests that an occupational or environmental inhalant or ingested substance is provoking or contributing to asthma. Depending on the complexities of diagnosis, treatment or the intervention required in the work environment, it may be appropriate in some cases for the specialist to manage the patient over a period of time or to co-manage with the primary care physician (PCP).

12. Determine Level of Asthma Control
    Recommendations

    - Clinicians should assign a level of control based on the most severe impairment or risk category of the patient.
    - Clinicians should assign the level of asthma control (well controlled, not well controlled, or poorly controlled) based on the degree to which both dimensions of the manifestations of asthma—impairment and risk—are minimized by therapeutic intervention.
    - Clinicians should determine their clinical actions (i.e., whether to maintain or adjust therapy) based on the level of control at the patient's follow-up assessment.

    See Table 5, "Assessing Asthma Control in Children 5-11 Years of Age," and Table 6, "Assessing Asthma Control in Youths 12 Years of Age through Adults," in the original guideline document.

13. Step Care of Pharmacologic Treatment
    Recommendations

    - Clinicians should follow the stepwise approach in asthma management therapy.

- Clinicians should use inhaled corticosteroids as the preferred treatment over leukotriene receptor antagonists in mild persistent asthma in adults and children.
- Clinicians should order annual influenza vaccination for patients with persistent asthma.

The aim of asthma therapy is to maintain control of asthma with the least amount of medication and hence minimize the risk for adverse effects. The stepwise approach to therapy, in which the dose and number of medications and frequency of administration are increased as necessary and decreased when possible, is used to achieve this control. Since asthma is a chronic inflammatory disorder of the airways with recurrent exacerbations, therapy for persistent asthma emphasizes efforts to suppress inflammation over the long term and prevent exacerbations. See tables below for management approach for asthma.

Based on data comparing leukotriene receptor antagonists (LTRAs) to inhaled corticosteroids, inhaled corticosteroids are the preferred treatment option for mild persistent asthma in adults and children. LTRAs are an alternative, although not preferred, treatment *[Guideline]*, *[High Quality Evidence]*, *[Systematic Review]*.

Vaccinations

Note: Annual influenza vaccinations are recommended for patients with persistent asthma *[Reference]*. Asthma is an independent risk factor for invasive pneumococcal disease *[Low Quality Evidence]*. The Advisory Committee on Immunization Practices (ACIP) recommends that persons aged 19 through 64 years who have asthma should receive a single dose of pneumococcal vaccine (PPSV23) (see http://www.cdc.gov/flu/protect/keyfacts.htm. [Accessed April 12, 2012]).

See Appendix B, "Usual Dosages for Quick-Relief Medications," in the original guideline document.

Table. Management Approach for Asthma in Children 5 to 11 Years of Age

Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
Asthma Education Environmental Control Management of Comorbidities					
Assess Asthma Control					
As-Needed Short-Acting Beta$_2$-Agonist					
<--------Step Down---------Asthma Control--------Step Up--------->					
Short-acting Beta$_2$-agonist as Needed	Low-dose ICS	Medium-dose ICS OR--->	Medium-dose ICS	High-dose ICS OR--->	High-dose ICS
	Alternative		Add One	Add One or More	Add
	Leukotriene Modifier		LABA	LABA	LABA +
			Leukotriene Modifier	Alternative	Oral Systemic Corticosteroid
				High-Dose ICS +	Alternative
				Leukotriene Modifier	High-Dose ICS +
					Leukotriene Modifier +
					Oral Systemic Corticosteroid +

Adapted from: Global Initiative for Asthma, 2006; National Heart, Lung, Blood Institute EPR-3, 2007.

Abbreviations: ICS, inhaled corticosteroids; LABA, Long-acting beta$_2$-agonist

Table. Management Approach for Asthma: 12 Years of Age and Older

Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
Asthma Education Environmental Control Management of Comorbidities					
Assess Asthma Control					
As-Needed Short-Acting Beta$_2$-Agonist					
<--------Step Down---------Asthma Control--------Step Up--------->					
Short-acting Beta$_2$-agonist As Needed	Low-dose ICS	Medium-dose ICS	Medium-dose ICS + LABA	High-dose ICS + LABA	High-dose ICS + LABA + Oral Corticosteroid
	Alternative	Alternative	Alternative	Add One or More	Add One or More
	Leukotriene Modifier	Low-Dose ICS + LABA	Medium-dose ICS + Leukotriene Modifier	Leukotriene Modifier	Leukotriene Modifier
		Low-Dose ICS + Leukotriene Modifier		Anti-IgE if applicable	Anti-IgE if applicable

Adapted from: Global Initiative for Asthma, 2006; National Heart, Lung, Blood Institute EPR-3, 2007.

Abbreviations: ICS, inhaled corticosteroids; LABA, Long-acting beta$_2$-agonist; IgE, immunoglobulin E

14. Asthma Education
    Recommendations

    - Clinicians must provide self-management education to give patients the skills necessary to control asthma and improve outcomes. When working with adult asthmatics, this education should include a written asthma action plan, patient self-monitoring and regular clinician follow-up *[Systematic Review]*.
    - Clinicians should integrate asthma self-management education into all aspects of asthma care, as it requires repetition and reinforcement *[Guideline]*.
    - A collaborative approach toward shared decision-making should always be undertaken (Refer to Appendix F, "ICSI Shared Decision-Making Model," in the original guideline document).
    - Discuss all potential side effects.

    Asthma self-management should:

    - Begin at the time of diagnosis and continue through follow-up care.
    - Involve all members of the health care team.
    - Introduce the key educational messages by the principal clinician, and negotiate agreements about the goals of treatment, specific medications, and the actions patients will take to reach the agreed-upon goals to control asthma.
    - Reinforce and expand key messages (e.g., the patient's level of asthma control, inhaler techniques, self-monitoring, and use of a written asthma action plan) by all members of the health care team.
    - Occur at all points of care where health professionals interact with patients who have asthma, including clinics, medical offices, emergency departments and hospitals, pharmacies, homes and community sites (e.g., schools, community centers).

    Regular review, by an informed clinician, of the status of the patient's asthma control is an essential part of asthma self-management

education. Teach and reinforce at every opportunity.

Supervised self-management (using patient education and adjustments of anti-inflammatory medication based on PEFR or symptoms coupled with regular medical review, utilization of adherence to medication) reduces asthma morbidity. This reduction includes lost work days, unscheduled office visits, and ED and hospital admissions *[Systematic Review]*, *[High Quality Evidence]*.

Refer to the original guideline document for additional information on asthma education including basic facts about asthma; how medications work (including potential side effects of inhaled steroids and $beta_2$-agonists [see also "Potential Harms" field]); inhaler technique; environmental control measures; written asthma action plan; need for adherence, and developing an active partnership with the patient and family.

A sample asthma action plan is attached in Appendix E of the original guideline document.

See also Minnesota Department of Health Action Plan at http://www.health.state.mn.us/asthma/ActionPlan.html (Accessed April 12, 2012).

15. Schedule Regular Follow-up Visits
    Asthma is a chronic inflammatory lung disease, and all chronic diseases need regular follow-up visits. Practitioners need to assess whether or not control of asthma has been maintained and if a step down in therapy is appropriate. Further, practitioners need to monitor and review the daily self-management and action plans, the medications, and the patient's inhaler and peak flow monitoring techniques. The exact frequency of visits is a matter of clinical judgment. If asthma is uncontrolled or a change in medication or clinical status has occurred, the patient should be followed in 2 to 6 weeks for an evaluation. A stable asthma patient should be followed at regular intervals of 1 to 6 months.

Emergency Department or Inpatient Management Algorithm Annotations

18. Assess Severity of Asthma Exacerbation
    See Annotation #5.

21. Initial Treatment
    See Annotation #8, "Management of Asthma Exacerbation."

25. Treatment (Incomplete Response)
    Recommendations

    - Systemic corticosteroids should be used for all patients who do not favorably respond to the initial $beta_2$-agonist therapy.
    - Anticholinergic therapy may increase lung function and may decrease hospital admission rate.

    Corticosteroids

    Parenteral and enteral administration of corticosteroids requires about 6 to 24 hours to be effective. Intravenous (IV) and oral routes of corticosteroid administration appear to be equivalent *[High Quality Evidence]*. Medium to high doses of corticosteroids appear to be better than low doses; however, there is still a large range, roughly 160 mg methylprednisolone per day or 2 mg/kg/day in children. There is no evidence to support very high doses of steroids *[Low Quality Evidence]*, *[High Quality Evidence]*. The National Asthma Education and Prevention Program guidelines recommend that patients admitted to the hospital should receive IV or oral steroids *[Guideline]*.

    There may be a role for inhaled high-dose corticosteroids in the emergency department in addition to the IV or oral route; however, the data do not support this as standard of care at this time *[High Quality Evidence]*, *[Systematic Review]*.

    In adult asthmatic cases where intolerance or non-compliance with oral steroid therapy is a concern, consider the use of intramuscular (IM) methylprednisolone *[High Quality Evidence]*.

    Anticholinergics

    Inhaled ipratropium bromide: adding multiple high doses of ipratropium bromide (0.5 mg nebulizer solution or 8 puffs by MDI in adults; 0.25 to 0.5 mg nebulizer solution or 4 to 8 puffs by MDI in children) to a selective short-acting $beta_2$-agonist produces additional bronchodilation, resulting in fewer hospital admissions, particularly in patients who have severe airflow obstruction *[High Quality Evidence]*, *[Systematic Review]*.

27. Treatment (Poor Response)

See Appendix A, "Dosages of Drugs for Asthma Exacerbations in the Emergency Medical Care or Hospital," in the original guideline document.

Recommendations

- There is no clinical advantage to continuous versus intermittent nebulization of albuterol in the treatment of acute asthma exacerbations *[High Quality Evidence]*, *[Systematic Review]*.
- Clinicians should consider bi-level positive airway pressure for patients with severe asthma exacerbations as this may prevent mechanical intubations *[High Quality Evidence]*.
- Clinicians may consider heliox as secondary therapy in asthma patients who do not respond to first-line therapies *[Systematic Review]*.
- Clinicians may consider ketamine for use in severe asthma exacerbations *[Low Quality Evidence]*.
- Clinicians should consider the use of magnesium sulfate in the treatment of severe acute asthma *[Meta-analysis]*, *[Low Quality Evidence]*, *[High Quality Evidence]*, *[Systematic Review]*.

Intermittent Nebulization versus Continuous Nebulization

Intermittent nebulization versus continuous nebulization in the treatment of acute asthma has been evaluated quite extensively. The data would suggest that these treatments are equally efficacious; however, there may be a trend toward improvement in patients with severe asthma using continuous nebulization. In a subgroup analysis of patients whose initial FEV_1 was less than 50% predicted, there was a statistically significant improvement in FEV_1 in patients treated with continuous nebulization versus intermittent nebulization *[High Quality Evidence]*. Similarly, in another subgroup analysis of patients whose initial PEFR was less than 200, there was a statistically significant improvement in PEFR and a decrease in hospital admissions in patients treated with continuous versus intermittent nebulization *[High Quality Evidence]*. However, in another subgroup of patients whose FEV_1 was less than 50% predicted, there was no difference in improvement in FEV_1 or hospital admissions in patients treated with continuous versus intermittent nebulization *[High Quality Evidence]*.

A meta-analysis suggests equivalence of continuous versus intermittent albuterol in treating asthma. This is determined by spirometry measurement and rates of admission to the hospital *[Meta-analysis]*. There does not seem to be any advantage of higher doses of albuterol for continuous nebulization. There was no difference in lung function in patients treated with 7.5 mg or 15 mg of albuterol *[High Quality Evidence]*. Utilizing albuterol and ipratropium bromide continuously versus albuterol alone demonstrated a trend toward improvement in reducing the length of stay in the emergency department and in hospital admission rates *[High Quality Evidence]*.

Bi-level Positive Airway Pressure (Bi-Level PAP)

Bi-level PAP therapy should be considered for patients presenting with an acute asthma exacerbation. Accumulating studies have shown a benefit in using bi-level PAP for patients presenting with non-cardiogenic respiratory failure. These studies included, but were not limited to, patients with asthma exacerbations. A study *[High Quality Evidence]* compared bi-level PAP ventilation plus conventional therapy versus conventional therapy in patients presenting with an acute asthma exacerbation. Patients in the bi-level PAP group showed a statistically significant improvement in lung function (measured by FEV_1), improved faster, and were less likely to require admission to the hospital and mechanical intubations.

Heliox

Heliox, a blend of helium and oxygen, is a low-density gas that has been shown in some studies to improve deposition of albuterol into distal airways when compared with nebulized albuterol with oxygen alone.

There is not enough evidence from large, prospective, randomized controlled trials to recommend heliox as first-line therapy in patients with asthma exacerbations. However, it is recommended that heliox be considered *[Systematic Review]* as a secondary therapy in patients with a severe asthma exacerbation who are not responding to first-line therapies.

Ketamine

Ketamine and propofol are anesthetic agents with neuroregulatory properties resulting in bronchodilation. The use of ketamine has shown benefit in improving airway parameters *[Low Quality Evidence]*, but increased side effects have resulted in longer hospitalizations *[Low Quality Evidence]*. Increased side effects of increased secretions, dysphoria and hallucinations are noted. Clinical data suggests that in the non-intubated patient the side effects may cancel benefit. Some reported case reports suggest benefit in intubated patients *[Low Quality Evidence]*. Well-controlled studies are required to make a clear strong recommendation for use. Use of ketamine has been pursued only in severe asthmatic exacerbations.

Magnesium Sulfate

The efficacy of magnesium sulfate has not been consistently demonstrated in randomized control trials. It has not been demonstrated to cause any harmful effects. In a recent multi-center trial, IV magnesium sulfate improved pulmonary function only in patients with severe asthma (FEV_1 less than 25%). It did not shorten length of hospital stay *[High Quality Evidence]*. In a systematic review, magnesium sulfate did not demonstrate improvement in PEFR, or in hospital length of stay. However, in a subset of patients with severe asthma exacerbations, PEFR, FEV_1 and length of stay were improved *[Systematic Review]*.There is insufficient evidence to support the routine use of IV magnesium in the emergency department setting *[Meta-analysis]*, *[Low Quality Evidence]*. However, since it is safe and inexpensive, it should be considered for use in patients with severe asthma exacerbations.

Leukotriene Modifiers

The evaluation of leukotriene modifiers for acute asthma care is in its infancy. Pulmonary function has been shown to improve more rapidly when a leukotriene administered orally is added to the standard therapy of asthma care ($beta_2$-agonists/corticosteroids) in emergency department settings *[Cost-Effectiveness Analysis]*, *[High Quality Evidence]*. More studies are needed to confirm these reports.

Montelukast in acute asthma management has been shown to improve pulmonary function in randomized controlled trials *[High Quality Evidence]*. However, statistical significance could not always be maintained.

The evidence is too preliminary to recommend leukotriene modifiers in acute asthma exacerbations.

29. Admit to Hospital?
Also see Annotation #10, "Does Patient Need ED or Inpatient Asthma Management?"

The decision when to discharge from the ED or admit to the hospital must be individualized and depends on response to treatment, pulmonary function, and socioeconomic factors. It is important to consider risk factors for asthma-related death *[Guideline]*. Actual length of stay in the ED will vary; some departments have the ability for more extended treatment and observation, provided there is sufficient monitoring and nursing care.

Response to initial treatment in the ED can be based on a repeat assessment approximately 60 to 90 minutes after initiating bronchodilator therapy, which is a better predictor of the need for hospitalization than is the severity of an exacerbation on presentation *[Low Quality Evidence]*. Evaluation includes the patient's subjective response, physical findings, O_2 saturation and measurement of airflow. Other aspects to consider include duration and severity of symptoms, course and severity of prior exacerbations, medications used at the time of the exacerbation, access to medical care and medications, adequacy of support and home conditions, and presence of psychiatric illness. Pretreatment O_2 saturation less than or equal to 70%, persisting respiratory acidosis, or severe obstruction that does not improve with the administration of sympathomimetics indicates the need for hospitalization *[Low Quality Evidence]*.

Discharge is appropriate if FEV_1 or PEFR has returned to greater than or equal to 70% personal best or predicted, and symptoms are minimal or absent. Patients with an incomplete response (FEV_1 or PEFR 40% to 69%), and with mild symptoms should be assessed individually and may be appropriate for discharge with consideration of the above factors. It is recommended that patients with a rapid good response be observed for 30 to 60 minutes after the most recent dose of bronchodilator to ensure stability of response before being discharged home.

30. Return to Annotations #25 and #27
Patients being admitted from the ED with an acute asthma exacerbation should be reassessed shortly after admission, with special emphasis on whether the patient is showing any clinical signs of improvement or deterioration (see Annotation #5, "Assess Severity of Asthma Exacerbation"). Objective data should include repeating of the patient's FEV_1 or PEFR. A complete physical exam should include emphasis on the patient's respiratory rate, air entry on lung exam, and the presence/absence of signs of increased work of breathing, such as supraclavicular or intercostal retractions.

Consider other illnesses and comorbidities. These may also cause dyspnea, chest tightness and wheezing.

- Viral pneumonitis
- Pneumothorax
- Pulmonary embolism
- Vocal cord dysfunction syndrome
- COPD

- Pulmonary edema
- Endobronchial obstruction (tumor or foreign body)
- Acute hypersensitivity pneumonitis
- Epiglottitis

[Low Quality Evidence]

32. Discharge Home
    Recommendation

    - At discharge, provide patients with necessary medications and education in how to use them, instruction in self-assessment, an action plan for managing recurrence of airflow obstruction, and a follow-up appointment.

    It is recommended that follow-up with an asthma care clinician occur within one week of discharge.

    Medications

    See the table below for hospital discharge checklist for patients with asthma exacerbations.

    - Inhaled $beta_2$-agonist every 2 to 6 hours.
    - Systemic corticosteroids are almost always the treatment of choice in patients with acute asthma exacerbation. Corticosteroids aid symptom resolution and prevent asthma relapse.
    - Initiate or increase anti-inflammatory medication:
        - Inhaled corticosteroids
            - The role of inhaled corticosteroids after an emergency department visit is controversial *[Systematic Review]*, *[High Quality Evidence]*. However, it is the consensus of the guideline development group that inhaled corticosteroids should be encouraged at the time of discharge.
        - Consider leukotriene modifiers as an additive therapy.
    - Antibiotics are not routinely used but may be warranted if patient has signs of acute bacterial infection, fever and purulent sputum.
    - Long-acting $beta_2$-agonists as monotherapy are NOT recommended.

    See Annotation #14 for asthma education and action plan.

    See Annotation #15 for follow-up care.

    Table. Hospital Discharge Checklist for Patients with Asthma Exacerbations

Intervention	Dose/Timing	Education/Advice
Inhaled medications (metered-dose inhaler + spacer/holding chamber)	Select agent, dose, and frequency (e.g., albuterol)	Teach purpose. Teach technique
$Beta_2$-agonist		Emphasize need for spacer/holding chamber.
Corticosteroids	Medium dose	Check patient technique.
Oral medications	Select agent, dose and frequency	Teach purpose. Teach side effects.
Peak flow meter	Measure a.m. and p.m. peak expiratory flow and record best of three tries each time.	Teach purpose. Teach technique. Distribute peak flow diary.
Follow-up visit	Make appointment for follow-up care with primary clinician or asthma specialist.	Advise patient (or caregiver) of date, time, and location of appointment within 7 days of hospital discharge.
Action plan	Before or at discharge	Instruct patient (or caregiver) on simple plan for actions to be taken when symptoms, signs, and PEF values suggest recurrent airflow obstruction.

Source: National Heart, Lung, Blood Institute EPR-2, 1997

Special Populations

Asthma in Pregnancy

The treatment plan of asthma management in pregnancy should include reducing medication toxicity, teratogenicity and preserving uteroplacenta circulation. Changes in the mother's asthma status are expected in almost half of patients, with half of these expecting a worsening of asthma status, particularly if previous pregnancies had similar outcomes. Typical changes of pregnancy—those of increased heart rate, respiratory rate and decreases in baseline CO_2 levels—can lead to underdiagnosing asthma severity if not recognized *[Low Quality Evidence]*.

The treatment of acute asthma in pregnancy follows the guidelines for acute asthma care, keeping in mind the goals of the management and changes in physiology.

Albuterol is the preferred short-acting $beta_2$-agonist and has not been linked to adverse fetal outcomes in follow-up studies. Inhaled corticosteroids (ICSs) are the preferred treatment for long-term control medication. Budesonide is the preferred ICS because more data are available on using budesonide in pregnant women than are available on other ICSs, and the data are reassuring *[Guideline]*. Systemic steroids, if used in the first trimester, may, though rarely, increase the frequency of cleft palate and possibly be associated with development of preeclampsia and prematurity. However, the risk to both mother and fetus of an unmanaged severe asthmatic attack overshadows the medication observed risks *[Low Quality Evidence]*.

Definitions:

Crosswalk between ICSI Evidence Grading System and GRADE

ICSI GRADE System	Previous ICSI System	
High, if no limitation	Class A:	Randomized, controlled trial
Low	Class B:	[observational]
		Cohort study
	Class C:	[observational]
		Non-randomized trial with concurrent or historical controls
Low		Case-control study
Low		Population-based descriptive study
*Low		Study of sensitivity and specificity of a diagnostic test
*Following individual study review, may be elevated to Moderate or High depending upon study design		
	Class D:	[observational]
Low		Cross-sectional study
		Case series
		Case report
Meta-analysis	Class M:	Meta-analysis

ICSI GRADE System	Previous ICSI System	Systematic review
Systematic Review		
Decision Analysis		Decision analysis
Cost-Effectiveness Analysis		Cost-effectiveness analysis
Low	Class R:	Consensus statement
Low		Consensus report
Low		Narrative review
Guideline	Class R:	Guideline
Low	Class X:	Medical opinion

Evidence Definitions

High Quality Evidence = Further research is very unlikely to change confidence in the estimate of effect.

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In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature will be used to inform the reader of other topics of interest. This literature is not given an evidence grade and is instead identified as a Reference throughout the document.

Clinical Algorithm(s)

The following detailed and annotated clinical algorithms are provided in the original guideline document :

- Diagnosis and Management of Asthma (Main Algorithm)
- Emergency Department or Inpatient Management

Scope

Disease/Condition(s)

Asthma

- Acute asthma exacerbation
- Chronic asthma

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Risk Assessment

Treatment

Clinical Specialty

Allergy and Immunology

Emergency Medicine

Family Practice

Internal Medicine

Pediatrics

Pharmacology

Pulmonary Medicine

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Emergency Medical Technicians/Paramedics

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Nurses

Pharmacists

Physician Assistants

Physicians

Respiratory Care Practitioners

Guideline Objective(s)

- To increase the rate of patients 5 years and older who have accurate assessment of asthma severity and control through the use of objective measures of lung function and symptoms
- To increase the rate of patients 5 years and older who have written asthma action plans, and timely and accurate assessment of asthma exacerbation
- To increase the rate of patients 5 years and older who have appropriate treatment and management of asthma in inpatient care settings
- To increase the rate of patients 5 years and older who have follow-up visits to ensure asthma control is maintained and appropriate therapy is administered following any visit for asthma or medication adjustment

Target Population

Patients over 5 years of age who present with asthma-like symptoms or have been diagnosed with asthma

Interventions and Practices Considered

Outpatient Management

Diagnostic Assessments (at Initial Diagnosis and Interval Evaluations)

1. Medical history
2. Physical examination
3. Use of validated asthma questionnaire, such as Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ) and Asthma Therapy Assessment Questionnaire (ATAQ)
4. Asthma triggers/allergens assessment
5. Pulmonary function tests: spirometry, including measurements of forced expiratory volume in 1 second (FEV_1), forced vital capacity (FVC), ratio of forced expiratory volume in 1 second to forced vital capacity (FEV_1/FVC), or peak expiratory flow rate (PEFR)
6. Additional clinical testing, such as arterial blood gases, chest x-ray, complete blood count with eosinophils, total immunoglobulin E, sputum exam, exhaled nitric oxide, bronchial provocation tests, electrolytes, electrocardiogram, and evaluation for gastroesophageal reflux disease (GERD)
7. Assessment of asthma severity, based on frequency and severity of symptoms, frequency and severity of exacerbations, and spirometry measurements
8. Specialty consultation as indicated

Management of Acute Asthma Exacerbations

1. Assessment of severity based on measures of lung function (FEV_1, PEFR, oxygen saturation), review of history and physical exam
2. Treatment with short-acting $beta_2$-agonist (albuterol) or alternatives (epinephrine, ipratropium, levalbuterol, systemic corticosteroids)
3. Assessment of response based on pulmonary function tests and symptoms

Treatment/Management

1. Annual influenza vaccination and a single dose of pneumococcal vaccine
2. Determining level of control
3. Stepped care management plan, where dose, medications, and frequency are increased as necessary and decreased when possible. Pharmacologic treatment options include the following (alone and in combination):
    - Short-acting inhaled $beta_2$-agonists
    - Inhaled corticosteroids (ICS)(low-dose, medium-dose, or high-dose)
    - Long-acting $beta_2$-agonists
    - Oral systemic corticosteroids
    - Leukotriene modifiers
    - Anti-immunoglobulin E if applicable
4. Asthma education emphasizing self-management and including need for adherence, inhaler technique, environmental control measures, written action plan, and a collaborative approach toward shared decision-making
5. Follow-up visits

Emergency Department and Inpatient Management

1. Assessment of severity of asthma exacerbation through history, physical exam, lung function measurements, and laboratory studies
2. Assessment of risk factors for death from asthma
3. Short-acting inhaled $beta_2$-agonists by metered dose inhaler or nebulizer
4. Intravenous or oral corticosteroids
5. Anticholinergics
6. Bi-level positive airway pressure (PAP) therapy, heliox, ketamine and magnesium sulfate in severe cases
   Note: The guideline developers considered, but did not find sufficient evidence to recommend, the following drugs in acute asthma

exacerbations: inhaled corticosteroids, leukotriene modifiers.

7. Discharge home with necessary medications and instructions how to use them, an action plan for managing recurrence of airflow obstructions, and a follow-up appointment
8. Hospital admission as indicated and patient reassessment
9. Continued treatment, consideration of other illnesses and comorbidities

Major Outcomes Considered

- Asthma symptom control
- Sensitivity and specificity of diagnostic tests
- Asthma morbidity measures such as level of physical activity, lost work days, unscheduled office visits, and emergency room and hospital admissions
- Side effects or complications of asthma pharmacotherapy
- Effect of asthma treatment on asthma score, oxygen saturation, and rate of hospitalization

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A consistent and defined process is used for literature search and review for the development and revision of Institute for Clinical Systems Improvement (ICSI) guidelines. The literature search was divided into two stages to identify systematic reviews (stage I) and randomized controlled trials, meta-analyses and other literature (stage II).

A literature search on diagnosing and treating asthma focused on systematic reviews in PubMed and Cochrane databases. Publication dates included November 2009 through November 2011. Limitations were human data only and English language publications. Search strategy can be seen in MeSH terms: asthma, diagnosis, therapy, therapeutics.

Broader searches were conducted on the use of FENO (fraction of expired nitric oxide) testing, asthma management clinics, and quality improvement programs for symptom management. Included were trial data and observational studies, guidelines and reviews. Search strategies can be seen in MeSH terms: FENO, organization and administration, disease management, symptom management, palliative care, clinics, specialty, ambulatory, guideline/meta-analysis/controlled trial/review.

A final search on patient education and self-management focused on both randomized controlled trials and systematic reviews in PubMed from January 2009 through March 2012. Results were limited to English language publications. Search strategy can be seen in MeSH terms: effective, patient education handout/ topic, self-management and self-monitoring.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Following a review of several evidence rating and recommendation writing systems, Institute for Clinical System Improvement (ICSI) has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

Crosswalk between ICSI Evidence Grading System and GRADE

ICSI GRADE System	Previous ICSI System	
High, if no limitation	Class A:	Randomized, controlled trial
Low	Class B:	[observational]
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	Class C:	[observational]
		Non-randomized trial with concurrent or historical controls
Low		Case-control study
Low		Population-based descriptive study
*Low		Study of sensitivity and specificity of a diagnostic test
*Following individual study review, may be elevated to Moderate or High depending upon study design		
	Class D:	[observational]
Low		Cross-sectional study
		Case series
		Case report
Meta-analysis	Class M:	Meta-analysis
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In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature will be used to inform the reader of other topics of interest. This literature is not given an evidence grade and is instead identified as a Reference throughout the document.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Guideline Development Process

A work group consisting of 6 to 12 members that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, and an Institute for Clinical Systems Improvement (ICSI) staff facilitator develops each document. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 work group members may be recruited from medical groups, hospitals or other organizations that are not members of ICSI.

The work group will meet for 7 to 8 three-hour meetings to develop the guideline. A literature search and review is performed and the work group members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and literature citations.

Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

The guideline developers reviewed a published cost analysis.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Critical Review Process

The purpose of critical review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the guideline. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes necessary across systems in their organization to implement the guideline.

All member organizations are expected to respond to critical review guidelines. Critical review of guidelines is a criterion for continued membership within the Institute for Clinical Systems Improvement (ICSI).

After the critical review period, the guideline work group reconvenes to review the comments and make changes, as appropriate. The work group prepares a written response to all comments.

Approval

Each guideline, order set, and protocol is approved by the appropriate steering committee. There is one steering committee each for Respiratory, Cardiovascular, Women's Health, and Preventive Services. The Committee for Evidence-based Practice approves guidelines, order sets, and protocols not associated with a particular category. The steering committees review and approve each guideline based on the following:

- Member comments have been addressed reasonably.
- There is consensus among all ICSI member organizations on the content of the document.
- Within the knowledge of the reviewer, the scientific recommendations within the document are current.
- When evidence for a particular recommendation in the guideline has not been well established, the work group identifies consensus statements that were developed based on community standard of practice and work group expert opinion.
- Either a critical review has been carried out, or to the extent of the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that a new round of critical review is not needed.

Once the guideline, order set, or protocol has been approved, it is posted on the ICSI Web site and released to members for use. Guidelines, order sets, and protocols are reviewed regularly and revised, if warranted.

Revision Process of Existing Guidelines

ICSI scientific documents are revised every 12 to 36 months as indicated by changes in clinical practice and literature. Every 6 months, ICSI checks with the work group to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

ICSI staff working with the work group to identify any pertinent clinical trials, meta-analysis, systematic reviews, or regulatory statements and other professional guidelines conduct a literature search. The work group will meet for 1-2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

A second review by members is indicated if there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations. If a review by members is not needed, the document goes to the appropriate steering committee for approval according to the criteria outlined above.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Accurate diagnosis and assessment of asthma severity and asthma control through the use of objective measures of lung function and

symptoms
- Increased rate of patients who have written asthma action plans and timely and accurate assessment of asthma exacerbation
- Improved treatment and management of emergency room (ER) and inpatient asthma
- Appropriate follow-up
- If clinicians, payers, community partners and patients follow these clinical guidelines and control asthma, countless children and adults will benefit through reduced suffering and hospitalizations.

Potential Harms

- Potential side effects from inhaled steroids include oral candidiasis and dysphonia.
- Beta$_2$-agonists may cause tachycardia, tremor, or nervousness.
- Individuals on long-term oral corticosteroids or frequent bursts of steroids need to be monitored for complications of corticosteroid use such as osteoporosis, hypertension, diabetes, and Cushing's syndrome.
- The height of individuals on corticosteroids should be monitored over time. The potential effect on linear growth in children is important because these drugs tend to be used over long periods of time. Cumulative data in children suggest that low-to-medium doses of inhaled corticosteroids may have the potential of decreasing growth velocity, but this effect is not sustained in subsequent years of treatment, is not progressive, and may be reversible.
- Inhaled glucocorticoids used to treat asthma have been shown to have deleterious effects on bone mineral density and markers of bone mineral metabolism. The risk of fracture attributable to inhaled or nasal glucocorticoids is uncertain.
- The use of ketamine has shown increased side effects resulting in longer hospitalization. Increased secretions, dysphoria, and hallucinations are noted. Clinical data suggest that in the nonintubated patient the side effects may cancel benefit.
- Systemic steroids in the first trimester of pregnancy may, though rarely, increase the frequency of cleft palate and possibly be associated with development of preeclampsia and prematurity. However, the risk to both mother and fetus of an unmanaged severe asthmatic attack overshadows the medication observed risks.

Contraindications

Contraindications

Long-acting beta$_2$-agonist (LABA) monotherapy should not be used in acute asthma exacerbations.

Qualifying Statements

Qualifying Statements

- The information contained in this Institute for Clinical Systems Improvement (ICSI) Health Care Guideline is intended primarily for health professionals and other expert audiences.
- This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in their individual case.
- This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the valuation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

Implementation of the Guideline

Description of Implementation Strategy

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Implementation Recommendations

Prior to implementation, it is important to consider current organizational infrastructure that address the following:

- System and process design
- Training and education
- Culture and the need to shift values, beliefs and behaviors of the organization.

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

- Facilitate timely and accurate diagnosis of asthma and asthma severity and control.
- Educate clinicians in the use of spirometry as a diagnostic tool.
- Educate clinicians and patients in the importance of developing a partnership using the Institute for Clinical Systems Improvement (ICSI) Collaborative Conversation™ for Shared Decision-Making model to establish and maintain an asthma action plan and assess adherence.

Implementation Tools

Chart Documentation/Checklists/Forms

Clinical Algorithm

Quality Measures

Quick Reference Guides/Physician Guides

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Related NQMC Measures

Diagnosis and management of asthma: percentage of patients with spirometry or peak flow at the last visit related to asthma.

Diagnosis and management of asthma: percentage of patients with assessment of asthma control using a validated questionnaire at the last visit related to asthma.

Diagnosis and management of asthma: percentage of hospitalized patients with asthma who are discharged on an inhaled anti-inflammatory medication.

Diagnosis and management of asthma: percentage of discharged patients with asthma who are readmitted to hospital within 30 days of discharge.

Diagnosis and management of asthma: percentage of patients with asthma who return to the emergency department for treatment of asthma within 30 days of last visit to the emergency department.

Diagnosis and management of asthma: percentage of patients with an emergency department visit or inpatient admission for an asthma exacerbation who are discharged from the emergency department or inpatient setting with an asthma discharge plan.

Diagnosis and management of asthma: percentage of patients whose asthma is not controlled or have change in medication or clinical status, who are seen by a health care clinician within two to six weeks.

Diagnosis and management of asthma: percentage of patients whose asthma is controlled who are seen by a health care clinician every one to six months.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

Sveum R, Bergstrom J, Brottman G, Hanson M, Heiman M, Johns K, Malkiewicz J, Manney S, Moyer L, Myers C, Myers N, Oâ€™Brien M, Rethwill M, Schaefer K, Uden D. Diagnosis and management of asthma. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2012 Jul. 86 p. [81 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1998 Jun (revised 2012 Jul)

Guideline Developer(s)

Institute for Clinical Systems Improvement - Nonprofit Organization

Guideline Developer Comment

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers; Allina Medical Clinic; Aspen Medical Group; Baldwin Area Medical Center; Brown Clinic; Center for Diagnostic Imaging/Medical Scanning Consultants; CentraCare; Central Lakes Medical Clinic; Chippewa County – Montevideo Hospital & Clinic; Cuyuna Regional Medical Center; Essentia Health; Fairview Health Services; Family HealthServices Minnesota; Family Practice Medical Center; Fergus Falls Medical Clinic; Gillette Children's Specialty Healthcare; Grand Itasca Clinic and Hospital; Hamm Clinic; HealthEast Care System; HealthPartners Central Minnesota Clinics; HealthPartners Medical Group & Regions Hospital; Hennepin County Medical Center; Hennepin Faculty Associates; Howard Young Medical Center; Hudson Physicians; Hutchinson Area Health Care; Hutchinson Medical Center; Integrity Health Network; Lake Region Healthcare Corporation; Lakeview Clinic; Mankato Clinic; MAPS Medical Pain Clinics; Marshfield Clinic; Mayo Clinic; Mercy Hospital and Health Care Center; Midwest Spine Institute; Minnesota Association of Community Health Centers; Minnesota Gastroenterology; Multicare Associates; New Richmond Clinic; North Central Heart Institute; North Clinic; North Memorial Health Care; Northwest Family Physicians; Obstetrics and Gynecology Specialists; Olmsted Medical Center; Park Nicollet Health Services; Planned Parenthood Minnesota, North Dakota, South Dakota; Quello Clinic; Raiter Clinic; Rice Memorial Hospital; Ridgeview Medical Center; River Falls Medical Clinic; Riverwood Healthcare Center; South Lake Pediatrics; Southside Community Health Services; Stillwater Medical Group; University of Minnesota Physicians; Winona Health

ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; e-mail: icsi.info@icsi.org; Web site: www.icsi.org .

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Guideline Committee

Respiratory Steering Committee

Composition of Group That Authored the Guideline

Work Group Members: Richard Sveum, MD (*Work Group Leader*) (Park Nicollet Health Services) (Allergy); Ken Johns, MD (Allina Medical Clinic) (Pediatrics and Allergy); Sarah Manney, DO (Essentia Health) (Pediatrics); James Bergstrom, MD (Fairview Health Services) (Internal Medicine and Pediatrics); Janet Malkiewicz, RN, AE-C (HealthPartners Medical Group and Regions Hospital) (Health Education); Lisbeth Ann Moyer, RPh (HealthPartners Medical Group and Regions Hospital) (Clinical Pharmacy, Medication Therapy Management); Michael Rethwill, MD (HealthPartners Medical Group and Regions Hospital) (Family Medicine); Gail Brottman, MD (Hennepin Faculty Associates) (Pediatrics); Marlis O'Brien, RRT, CPFT, AE-C (Mayo Clinic) (Respiratory Therapist/Asthma Educator); Mary Heiman, LSN, RN, MS (Minneapolis Public Schools) (School Nurse); Nicolette Myers, MD (Park Nicollet Health Services) (Pulmonology); Kathryn Schaefer, MD (South Lake Pediatrics) (Pediatrics); Donald Uden, PharmD, FCCP (University of Minnesota, School of Pharmacy) (Department of Pharmaceutical Care and Health Systems); Myounghee Hanson, BA (Institute for Clinical Systems Improvement) (Clinical Systems Improvement Facilitator); Cassie Myers (Institute for Clinical Systems Improvement) (Systems Improvement Coordinator)

Financial Disclosures/Conflicts of Interest

Disclosure of Potential Conflicts of Interest

James Bergstrom, MD, Work Group Member
Internal Medicine and Pediatrics, Fairview Health Services
National, Regional, Local Committee Affiliations: None
Guideline-Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Gail Brottman, MD, Work Group Member
Pediatric Medicine, Hennepin Faculty Associates
National, Regional, Local Committee Affiliations: Board member, American Lung Association – MN; Member, American Lung Association

National Assembly
Guideline-Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Mary Heiman, LSN, RN, MS, Work Group Member
Minneapolis Public Schools
National, Regional, Local Committee Affiliations: Medica Public Programs steering group member on MN child/family public assistance programs; Board member, School Nurse Organization of MN; School Nurse Organization of MN annual conference reimbursement; Member, U of MN School of Nursing, Children with Special Health Care Needs advisory council
Guideline-Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Ken Johns, MD, Work Group Member
Pediatrician and Allergist, Allina
National, Regional, Local Committee Affiliations: None
Guideline-Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Janet Malkiewicz, RN, BSN, AE-C, Work Group Member
Respiratory Nurse Clinician, Health Education, HealthPartners Medical Group and Regions Hospital
National, Regional, Local Committee Affiliations: None
Guideline-Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Sarah Manney, DO, FAAP, Work Group Member
Pediatrician, Essentia Health
National, Regional, Local Committee Affiliations: None
Guideline-Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Lisbeth Ann Moyer, RPh, Work Group Member
Clinical Pharmacist, Medication Therapy Management, HealthPartners Medical Group and Regions Hospital
National, Regional, Local Committee Affiliations: None
Guideline-Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Nicolette Myers, MD, Work Group Member
Pulmonologist, Park Nicollet
National, Regional, Local Committee Affiliations: None
Guideline-Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Marlis O'Brien, RRT, AE-C, CPFT, Work Group Member
Respiratory Therapist, Mayo Clinic
National, Regional, Local Committee Affiliations: None
Guideline-Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Michael Rethwill, MD, Work Group Member

Family Medicine, HealthPartners Medical Group and Regions Hospital
National, Regional, Local Committee Affiliations: None
Guideline-Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Kathryn Schaefer, MD, Work Group Member
Pediatrician, South Lake Pediatrics
National, Regional, Local Committee Affiliations: None
Guideline-Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Richard Sveum, MD, Work Group Leader
Allergist, Park Nicollet Health Services
National, Regional, Local Committee Affiliations: Board member, American Lung Association of the Upper Midwest
Guideline-Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Donald Uden, PharmD, FCCP, Work Group Member
Department of Pharmaceutical Care and Health Systems, University of MN
National, Regional, Local Committee Affiliations: Board member, American Lung Association – MN Leadership Board
Guideline-Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: Consultant, Point of Care Decision Support on Asthma guidelines software support; Educational presentation for American Lung Association on "Asthma Medications" given in January 2012

Guideline Status

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This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of asthma. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2010 Jun. 64 p.

Guideline Availability

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site .

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org ; e-mail: icsi.info@icsi.org.

Availability of Companion Documents

The following are available:

- Diagnosis and management of asthma. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement; 2012 Jul. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site .
- Health care order set: admission for asthma order set. Bloomington (MN): Institute for Clinical Systems Improvement; 2012 Jul. 3 p. Electronic copies: Available from the ICSI Web site .

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org ; e-mail: icsi.info@icsi.org.

Additionally, a sample asthma action plan and an ICSI shared decision-making model are available in the appendices of the original guideline

document .

Patient Resources

None available

NGC Status

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